

**In the claims**

Please amend the claims as follows:

- 1 1. A solid pharmaceutical dosage form for oral administration, the dosage form  
2 comprising:  
3 an extended release layer comprising a biguanide; and  
4 an immediate release layer comprising a glitazone.
- 1 2. The dosage form of claim 1, wherein the biguanide comprises one or more of  
2 metformin, phenformin, and buformin.
- 1 3. The dosage form of claim 1, wherein the biguanide is metformin.
- 1 4. The dosage form of claim 1, wherein the glitazone comprises one or more of  
2 pioglitazone, rosiglitazone, troglitazone, ciglitazone and englitazone.
- 1 5. The dosage form of claim 4, wherein the glitazone is pioglitazone.
- 1 6. The dosage form of claim 1, wherein after oral administration the biguanide is  
2 released over a period of about 4 to about 36 hours.
- 1 7. The dosage form of claim 6, wherein the biguanide is released over a period of  
2 about 8 to about 24 hours.
- 1 8. Cancelled.
- 1 9. Cancelled.
- 1 10. Cancelled.
- 1 11. The dosage form of claim 1, wherein the extended release layer comprises a  
2 matrix.

- 1 12. The dosage form of claim 11, wherein the matrix comprises a uniform mixture of  
2 the biguanide and one or more rate controlling polymers.
- 1 13. Cancelled.
- 1 14. Cancelled.
- 1 15. Cancelled.
- 1 16. The dosage form of claim 1, wherein the biguanide is layered onto a  
2 pharmaceutically inert core or seed.
- 1 17. The dosage form of claim 16, wherein the inert core or seed is hydrosoluble or  
2 hydroinsoluble.
- 1 18. The dosage form of claim 1, wherein the immediate release outer layer further  
2 comprises film-forming polymers and optionally other pharmaceutically  
3 acceptable excipients.
- 1 19. Cancelled.
- 1 20. The dosage form of claim 18, wherein the pharmaceutically acceptable excipients  
2 comprises one or more of plasticizers, opacifiers and colorants.
- 1 21. The dosage form of claim 1, further comprising one or more of sulfonylurea,  
2 insulin, alpha-glucosidase inhibitors, meglitinides, fibrates, statins, squalene  
3 synthesis inhibitors and angiotensin-converting enzyme inhibitors.
- 1 22. The dosage form of claim 1, further comprising a wetting agent in the immediate  
2 release layer, wherein the immediate release layer comprises the glitazone and the  
3 wetting agent in a weight ratio ranging from about 10:1 to about 1:25.
- 1 23. Cancelled.
- 1 24. Cancelled.
- 1 25. Cancelled.

- 1 26. Cancelled.
- 1 27. Cancelled.
- 1 28. The dosage form of claim 1, wherein the extended release layer comprises a core  
2 and the immediate release layer covers at least a portion of the core.
- 1 29. The dosage form of claim 1, wherein the dosage form comprises a bilayered  
2 dosage form.
- 1 30. A process for preparing a solid, orally administered pharmaceutical dosage form  
2 of an extended release core of a biguanide and an immediate release layer of a  
3 glitazone, the process comprising:  
4 a. dispersing the biguanide in a solid matrix to form a core having a surface; and  
5 b. layering the immediate release layer of the glitazone on the surface of the  
6 core.
- 1 31. The process of claim 30, wherein layering the immediate release layer further  
2 comprises layering one or more wetting agents.
- 1 32. The process of claim 31, wherein the glitazone and the one or more wetting  
2 agents are present in the immediate release layer in a weight ratio ranging from  
3 about 10:1 to about 1:25.
- 1 33. Cancelled.
- 1 34. Cancelled.
- 1 35. Cancelled.
- 1 36. Cancelled.
- 1 37. Cancelled.
- 1 38. Cancelled.
- 1 39. Cancelled.

- 1 40. Cancelled.
- 1 41. Cancelled.
- 1 42. Cancelled.
- 1 43. Cancelled.
- 1 44. Cancelled.
- 1 45. Cancelled.
- 1 46. Cancelled.
- 1 47. Cancelled.
- 1 48. Cancelled.
- 1 49. Cancelled.
- 1 50. Cancelled.
- 1 51. Cancelled.
- 1 52. Cancelled.
- 1 53. Cancelled.
- 1 54. Cancelled.
- 1 55. Cancelled.
- 1 56. Cancelled.
- 1 57. The process of claim 30, further comprising placing a seal-coat over the core,  
2 wherein the seal-coat comprises hydrophilic polymers.
- 1 58. A process for preparing a bilayered, solid, orally administered pharmaceutical  
2 dosage form of a biguanide and a glitazone, the process comprising:

- 3           a.       dispersing the biguanide in an extended release carrier base material;
- 4           b.       separately dispersing the glitazone in an immediate release carrier base
- 5                   material; and
- 6           c.       compressing the material of step a and step b to form bilayered tablet.

1   59.    The process of claim 58, wherein the immediate release carrier base material  
2           further comprises one or more wetting agents before or after dispersing the  
3           glitazone.

1   60.    The process of claim 59, wherein the glitazone and the one or more wetting  
2           agents are present in a weight ratio ranging from about 10:1 to about 1:25.

1   61.    Cancelled.

1   62.    Cancelled.

1   63.    Cancelled.

1   64.    Cancelled.

1   65.    Cancelled.

1   66.    Cancelled.

1   67.    Cancelled.

1   68.    Cancelled.

1   69.    Cancelled.

1   70.    Cancelled.

1   71.    Cancelled.

1   72.    Cancelled.

1   73.    Cancelled.

1 74. Cancelled.

1 75. Cancelled.

1 76. Cancelled.

1 77. Cancelled.

1 78. Cancelled.

1 79. Cancelled.

1 80. Cancelled.

1 81. Cancelled.

1 82. Cancelled.

1 83. Cancelled.

1 84. Cancelled.

1 85. Cancelled.

1 86. A method of treating non-insulin dependent diabetes mellitus in a patient in need  
2 thereof, the method comprising administering a solid, pharmaceutical dosage  
3 form of the combination of a biguanide and a glitazone, wherein the dosage form  
4 provides an extended-release of the biguanide and an immediate release of the  
5 glitazone.

1 87. The method of claim 86, wherein the biguanide comprises one or more of  
2 metformin, phenformin, and buformin.

1 88. Cancelled.

1 89. The method of claim 86, wherein the glitazone comprises one or more of  
2 pioglitazone, rosiglitazone, troglitazone, ciglitazone and englitazone.

1 90. Cancelled.

1 91. The method of claim 86, wherein after oral administration the biguanide is  
2 released over a period of about 4 to about 36 hours.

1 92. The method of claim 86, wherein the biguanide is released over a period of about  
2 8 to about 24 hours.

1 93. Cancelled.

1 94. The method of claim 86, wherein the dosage form further comprises one or more  
2 of sulfonylurea, insulin, alpha-glucosidase inhibitors, meglitinides, fibrates,  
3 statins, squalene synthesis inhibitors and angiotensin-converting enzyme  
4 inhibitors.